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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Rea et al.

Serial No.: 09/666,430

Filed: September 21, 2000

For: DENDRITIC CELL ACTIVATED IN THE PRESENCE OF GLUCOCORTICOID HORMONES ARE CAPABLE OF SUPPRESSING ANTIGEN-SPECIFIC T CELL RESPONSES

Confirmation No.: 6289

Examiner: G. Ewoldt

Group Art Unit: 1644

Attorney Docket No.: 3157-4205.1US

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COMMUNICATION PROVIDING AMENDED SUMMARY OF CLAIMED SUBJECT MATTER IN AN APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As indicated at MPEP § 1205.03(B), "[w]hen the Office holds the brief to be defective solely doe to appellant's failure to provide a summary of the claims subject matter as required . . ., an entire new brief need not, and should not be filed; rather a paper providing a summary of the clamed subject matter will suffice."

Pursuant to the above, applicants herein provide a summary of the claimed subject matter in compliance with 35 C.F.R. § 41.37(c)(1)(v), and request that this version of the summary of

the claimed subject matter replace the section of the same name in the Appeal Brief filed August 14, 2006.

Further, as this paper is submitted within two (2) months of mailing date of the Notice of Non-Compliant Appeal Brief (mailed September 6, 2006), submitted herewith is a Petition for Extension of Time (1 month) pursuant to 37 C.F.R. § 1.136(a).

(5) SUMMARY OF CLAIMED SUBJECT MATTER

Independent claims 1, 40, 51, 56, 64, 65, 69, and 71 relate to means and methods for immunotherapy. Independent claim 1 provides a method for preparing a pharmaceutical composition for reducing an unwanted T-cell response in a host, said method comprising: culturing peripheral blood monocytes from said host to differentiate into dendritic cells; activating said dendritic cells with a means for reducing IL-12p40 production by said dendritic cells; loading said dendritic cells with an antigen against which said T-cell response is to be reduced; and forming a pharmaceutical composition comprising said loaded, activated dendritic cells for administration to said host. *See*, Substitute Specification, mailed March 18, 2003, at page 6, lines 22 through page 7, line 2 and page 10, line 19 through page 11, line 2.

Independent claim 40 provides method for preparing a pharmaceutical composition for reducing an unwanted T-cell response in a host against an antigen, said method comprising: culturing peripheral blood monocytes from said host to differentiate into dendritic cells; activating said dendritic cells with a glucocorticoid capable of activating a glucocorticoid receptor; bringing said dendritic cells into contact with an antigen against which said T-cell response is to be reduced; and forming a pharmaceutical composition comprising said loaded, activated dendritic cells. *Id.* at page 6, lines 22 through page 7, line 2; page 12 lines 8-17; page 11, lines 10-13; and page 12, lines 20-25.

Independent claim 51 provides a method for obtaining a dendritic cell capable of tolerizing a T-cell for an antigen, comprising: providing said dendritic cell with a substance capable of activating a glucocorticoid receptor; activating said dendritic cell; and providing said dendritic cell with said antigen, wherein said dendritic cell is capable of tolerizing a T-cell for

said antigen. *Id.* at page 6, lines 22 through page 7, line 2; page 12 lines 8-17; page 11, lines 10-13; and page 12, lines 5-25

Independent claim 56 provides a method for preparing an isolated dendritic cell, said method comprising: isolating peripheral blood monocytes from a subject; culturing the peripheral blood monocytes to differentiate into dendritic cells; activating the dendritic cells with a glucocorticoid; loading the dendritic cells with an antigen; and isolating said loaded, activated dendritic cells. *Id.* at page 6, lines 22 through page 7, line 2; page 7, lines 13-19; page 8 lines 20-21; and page 11, line 29 through page 12, line 4.

Independent claim 64 provides a method for preparing a dendritic cell capable of tolerizing a T-cell, said method comprising: culturing peripheral blood monocytes to differentiate into dendritic cells; activating the dendritic cells with dexamethasone; and loading the dendritic cells with an antigen which is MHC-matched to a clonal T-cell, wherein the dendritic cells are capable of tolerizing the clonal T-cell in vitro to the antigen. *Id.* at page 6, lines 22 through page 7, line 12; and page 9, lines 7-9.

Independent claim 65 provides a method for preparing a dendritic cell for tolerizing a T-cell in a graft or transplant recipient, said method comprising: culturing peripheral blood monocytes from said graft or transplant recipient to differentiate into dendritic cells; activating said dendritic cells; and loading said dendritic cells with an antigen against which said T-cell is to be tolerized. *Id.* at page 6, lines 22 through page 7, line 12; and page 9, lines 1-9.

Independent claim 69 provides a method for preparing a pharmaceutical composition for reducing an unwanted T-cell response to an antigen in a host, said method comprising: culturing peripheral blood monocytes from said host to differentiate into dendritic cells *in vitro*; contacting said dendritic cells *in vitro* with an antigen against which said T-cell response is to be reduced, thereby loading said dendritic cells with the antigen; contacting said dendritic cells with dexamethasone; activating the CD40 receptor on said dendritic cells; and forming a pharmaceutical composition comprising said loaded, activated dendritic cells. *Id.* at page 6, lines 22 through page 7, line 2; page 7, lines 13-19 and lines 25-30; page 8 lines 20-21; page 11, line 4 through page 12, line 4; page 12, lines 21-25 and original claim 13.

Independent claim 77 provides a method for obtaining a dendritic cell capable of tolerizing a T-cell for an antigen, the method comprising: contacting a dendritic cell with

dexamethasone *in vitro*; activating the dendritic cell through the CD40 receptor; and contacting the dendritic cell with an antigen, thereby loading the dendritic cell with the antigen, and forming a dendritic cell capable of tolerizing a T-cell for the antigen. *Id.* at page 6, lines 22 through page 7, line 2; page 7, lines 13-19 and lines 25-30; page 8 lines 20-21; page 11, line 4 through page 12, line 4; page 12, lines 21-25 and original claim 13.

As set forth in 37 C.F.R. 41.73 (c) (1) (vii), every means plus function claim must be identified and the structure materials or acts described in the specification corresponding to each claimed function must be set forth with reference to the specification. The current application contains a single means plus function claim, to wit: claim 1. The relevant means plus function language of claim 1 recites "activating said dendritic cells with a means for reducing IL-12p40 production by said dendritic cells."

The specification, in Example 3 (*See*, Substitute Specification, mailed March 18, 2003, at page 10, line 19 through page 11, line 2), indicates that dexamethasone, a known compound, has the ability to reduce reducing IL-12p40 production by a dendritic cell, and is thus a disclosed means to accomplish this function. Further, the Examiner, in the Office Action mailed July 26, 2005, at Page 5, agrees dexamethasone is a disclosed means for the function of reducing IL-12p40 production by said dendritic cells.

CONCLUSION

Applicants respectfully submit that the above provided summary of the claimed subject matter complies 35 C.F.R. § 41.37(c)(1)(v), and request that this version of the summary of the claimed subject matter replace the section of the same name in the Appeal Brief filed August 14, 2006. If any questions remain after consideration of the foregoing, or the Office should determine that there are any additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact the applicant's undersigned attorney at the address or phone number provided herein.

Respectfully submitted,

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